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10/529,984	03/31/2005	Emadeldin M. Hassan	B4700-597US	6260

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EXAMINER	
SHTERENGARTS, SAMANTHA L	
ART UNIT	PAPER NUMBER
1626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,984	HASSAN ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 24-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 24-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendments filed on July 22, 2008 are acknowledged.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claim 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Hirai et al. (U.S. 3,826,666) and further in view of Matthews et al. (U.S. 4,816,259).

With respect to Claim 20, Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer (gelatin), an acid-insoluble polymer (hydroxypropyl methylcellulose phthalate), and an alkaline aqueous solvent (ammonia solution) (pg. 5, lines 21-40; Examples). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell (pg. 5, lines 25-27),

therefore, is considered to be about 30:70 (42%). Venkateswara et al. fails to expressly disclose the final pH of the gel mass is less than or equal to about 9 pH units.

Hirai et al. further discloses the final pH of the gel mass is less than or equal to about 9 pH units. (col. 3, lines 12-13). It would have been obvious to one of ordinary skill in the art to modify the final pH of the gel mass in order to prevent the alteration of the gelatin (col. 3, lines 6-8). The modified Venkateswara et al. also fails to expressly disclose the moisture content of the capsule shell being 8-10%. Matthews et al. teaches it is well known for enteric soft capsule shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). It would have been obvious to one of ordinary skill in the art to modify the moisture content of the shell in order to create the desired wall thickness, as taught by Hirai et al. (col. 3, lines 51-58).

Response to Arguments

3. Applicant's arguments filed July 22, 2008 have been fully considered but they are not persuasive for the following reasons.

Applicants cite lines 25-27 of Venkateswara et al., which describe a preferred embodiment, "The amount of such enteric polymer employed may range from 5.0 to 40.0 percent, preferably 5.0 -25.0 percent by weight with reference to the dried shell." Applicants say that Venkateswara et al. does not teach or suggest any ratio of acid-insoluble polymer to film-forming polymer. Since the percentage of 40.0 percent by weight is disclosed, it is suggested by Venkateswara et al. that there would be 40% of acid-insoluble polymer in the composition; however, Applicant is correct that we cannot assume that the other 60% is entirely the film-forming polymer, and that is not what is being assumed here. Example 2 on page 9 of Venkateswara et al. shows a ratio of 10:30 (which may be restated as 30:90 as Applicants have

shown), which is comparable to the lower end of the ratio range as claimed by Applicants. While Venkateswara et al. does not disclose an upper end of the ratio that is comparable to the instantly claimed ratios, it would be obvious for one of ordinary skill in the art to modify the amounts of water soluble polymer and acid-insoluble polymer present in the composition. The examples taught in Venkateswara et al. have modified the amounts, further suggesting to one of ordinary skill that variation of these ratios would allow one or ordinary skill to experiment in order to provide a capsule with the property of being an insoluble capsule when in the stomach acid but also rapidly dissolving when it comes in contact with the alkaline secretions of the intestine, as taught by Hirai (col. 3, lines 36-45). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Furthermore, Applicants states that the secondary references do not cure the deficiencies of Venkateswara et al. because they are cited only for relating to the pH of the gel mass and the moisture content of the capsule shell. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Hirai et al. (U.S. 3,826,666) and in further view of Matthews et al. (U.S. 4,816,259).

(Claim 20 rejection restated from section 2 above).

With respect to Claim 20, Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer (gelatin), an acid-insoluble polymer (hydroxypropyl methylcellulose phthalate), and an alkaline aqueous solvent (ammonia solution) (pg. 5, lines 21-40; Examples). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell (pg. 5, lines 25-27), therefore, is considered to be about 30:70 (42%). Venkateswara et al. fails to expressly disclose the final pH of the gel mass is less than or equal to about 9 pH units.

Hirai et al. further discloses the final pH of the gel mass is less than or equal to about 9 pH units. (col. 3, lines 12-13). It would have been obvious to one of ordinary skill in the art to modify the final pH of the gel mass in order to prevent the alteration of the gelatin (col. 3, lines 6-8). The modified Venkateswara et al. also fails to expressly disclose the moisture content of the capsule shell being 8-10%. Matthews et al. teaches it is well known for enteric soft capsule

shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). It would have been obvious to one of ordinary skill in the art to modify the moisture content of the shell in order to create the desired wall thickness, as taught by Hirai et al. (col. 3, lines 51-58).

Claims 24-25, 27-33, 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Okajima in view of Hirai et al. (U.S. 3,826,666) and in further view of Matthews et al. (U.S. 4,816,259).

Okajima et al. discloses a gel mass composition comprising a film-forming, water-soluble polymer (gelatin or hydroxypropyl methylcellulose), an acid-insoluble polymer (cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate), an alkaline aqueous solvent (dilute aqueous solution of ammonium hydroxide), and optionally a plasticizer (PEG), and optionally, a coloring agent (col. 3, lines 54-64; col.4, lines 31-38). Okajima et al. illustrates in Example 2 the ratio of acid-insoluble polymer to film-forming polymer being 50:50; however fails to expressly disclose the ratio being from about 30:70 to about 45:55 by weight. Hirai et al. discloses the ratio is in a range of 1:1.5 to 1:4 (col. 3, lines 46-48), and therefore can be within the claimed range (1:1.5).

With respect to claims 24 and 25, Venkateswara et al. teaches gelatin as the film-forming water-soluble polymer, which is proteinaceous. With respect to claims 27-33, Venkateswara et al. and Okajima et al. teach hydroxypropyl methylcellulose as a carbohydrate to be used as the film-forming, water-soluble polymer. Venkateswara et al. and Okajima et al. teach the acid-insoluble polymer as phthalate, and both teach a plasticizer selected from the group in instant claim 30. Venkateswara et al. and Okajima et al. teach ammonia as an alkaline aqueous solution,

which is a volatile alkali. Finally, Okajima et al. teaches the final pH of the gel mass is less than or equal to about 9 pH units (col. 4, line 10).

With respect to claims 36-38, as discussed above, the modified teachings of Venkateswara et al. and Okajima et al. address all limitations of claim 20; however, fail to expressly disclose the gel mass composition used in producing an enteric soft capsule shell. The modified Okajima et al. does disclose the claimed structural feature of the gel mass composition, and therefore, is considered to be capable of producing an enteric soft capsule shell. The modified Okajima also fails to expressly disclose the moisture content being about 8%. Matthews et al. teaches it is well known in the art for enteric soft capsules to have a moisture content of about 8-10% (col. 2, line 18; col.4, lines 19-20). It would have been obvious to one of ordinary skill in the art to modify the moisture content in order to create the desired wall thickness, as taught by Okajima et al. (col. 4, lines 15-20).

With respect to claim 39, Venkateswara et al. discloses in the examples an enteric soft capsule having a plasticizer and a film-forming water soluble polymer within the claimed ranges (Examples). With respect to claim 40, the modified Okajima and Venkateswara et al. fail to expressly disclose the ratio of plasticizer to film-forming water soluble polymer being 1:3. However, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Okajima (U.S. 4,138,013) in view of Hirai et al. (U.S. 3,826,666) and further in view of Shank (U.S. 4,500,453).

As discussed above, the modified teachings of Venkateswara et al. and Okajima et al. address all limitations of claims 20 and 24-25; however, fail to expressly disclose the gelatin is extracted from animal bones or skins and has about 100-250 blooms. Shank teaches it is well known in the art that gelatin used is from animal bones (col. 1, lines 22-26). Shank further teaches it is well known in the art for hard enteric capsules to be made with gelatin having about 100-250 blooms (col.1, line 67 - col. 2, line 21). It would have been obvious design choice to one of ordinary skill in the art to utilize animal gelatin with blooms between 100-250 blooms in order to create a hard capsule.

Claim 34 is rejected as under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Okajima (U.S. 4,138,013) in view of Hirai et al. (U.S. 3,826,666) and further in view of Itoh (U.S. 5,194,464).

As discussed above, the modified teachings of Venkateswara et al. and Okajima et al. address all limitations of claim 20; however, fails to expressly disclose the alkaline aqueous solution being a hydroalcoholic solution. Itoh et al. teaches using a mixture of ethanol and water as a solvent to dissolve hydroxypropyl methylcellulose phthalate (col. 3, lines 26-30). It would have been obvious to one of ordinary skill in the art to modify the solution used in order to provide a suitable solvent for dissolving the acid-insoluble polymer.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626